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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,428	04/06/2001	Seth J. Orlow	291472.124US1	6098

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WILMERHALE/BOSTON
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BOSTON, MA 02109

EXAMINER	
SOROUSH, ALI	

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
05/23/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)
	09/827,428	ORLOW ET AL.
	Examiner	Art Unit
	ALI SOROUSH	1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 14 February 2008.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 82 and 93-107 is/are pending in the application.

4a) Of the above claim(s) 93,94 and 97-104 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 82,95,96 and 105-107 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

0DETAILED ACTION

Acknowledgement of Receipt

Applicant's response filed on 02/14/2008 to the Office Action mailed on 11/02/2007 is acknowledged.

Status of the Claims

Claims 1-81 and 83-92 are cancelled, Claims 93, 94, and 97-104 are withdrawn as being drawn to non-elected subject matter and claim 82 is currently amended.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Applicant Claims
2. Determining the scope and contents of the prior art.
3. Ascertaining the differences between the prior art and the claims at issue; and resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 82 and 106-107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsia et al. (US Patent 5498607, Published 03/12/1996) in view of Kagan (US Patent 3389051, Published 06/18/1968).

Applicant Claims

Applicant claims a pharmaceutical composition as an ointment, cream, lotion, or emulsion for topical application comprising a compound of formulas II-VIII (as described in the instant claim 82).

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Hsia et al. teaches the topical application of at least one phospholipid in the form of a lotion, cream, gel and ointment for the treatment and prevention of atherosclerosis. (See abstract and claim 4). The composition includes a pharmaceutically acceptable carrier and optionally other ingredients such as perfumes, coloring agents, water, and absorption enhancers. (See column 3, Lines 1-2 and 21-25).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Hsia et al. lacks a teaching of a composition comprising a compound of formulas II-VIII. This deficiency is cured by the teachings of Kagan.

Kagan teaches a method of treating atherosclerosis by reducing cholesterol in the body. (See column 2, Lines 16-25 and 36-40). The composition used for the treatment atherosclerosis has as its principal ingredient 3β-(diethylaminoethoxy)-5-

androsten-17-one in a variety of unit dosage forms including suspensions in aqueous or oil vehicles. (See column 1, Lines 69-71, Formula I and column 4, Lines 69-75).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Hsia et al. and Kagan. One would be motivated to combine the teachings because both Hsia et al. and Kagan treat the same condition, atherosclerosis. One would be motivated to combine the compound of Kagan with the composition of Hsia et al. in order to increase cholesterol-lowering activity of the composition of Hsia et al. With regard to the limitation that the compound is intended to reduce skin pigmentation, this limitation is an intended use limitation and is not given patentable weight in a composition claim. For the foregoing reasons the instant composition would have been obvious to one of ordinary skill in the art at the time of the instant invention.

Response to Applicants Arguments

Applicant has argued that the disclosure of Kagan is directed for oral administration or injection but does not teach or suggest topical administration of the disclosed cholesterol lowering compositions. Therefore, applicant argues that there is no motivation or expectation of success for combination with the teachings of Hsia et al. Applicant’s argument has been fully considered and found not to be persuasive. Kagan teaches, “the novel compositions are suitably presented for administration in unit dosage form as … suspensions in aqueous or oil vehicles ... and the like." (See column 4, Lines 69-75). It is therefore the examiners position that it would have been obvious to one of ordinary skill in the art at the time of the instant invention that the compositions of

Kagan can be applied topically. Further, it is well known in the art that steroids and steroid derivatives can be formulated into topical formulations and therefore one would expect success in the formulation of the compositions taught by Kagan when combined with the teachings of Hsia et al.

Applicant further argues the applicant's invention unexpectedly has been shown to be useful for reducing skin pigmentation and therefore such as a composition would not have been obvious to one of ordinary skill in the art at the time of the instant invention. Applicant's argument has been fully considered and found not to be persuasive. The ability of the composition to reduce skin pigmentation is an intended use of the composition and is not given patentable weight in claims to a pharmaceutical composition. For the foregoing reasons the instant rejection of claims 82 and 106-107 under 35 U.S.C. 103(a) **is maintained**.

2. Claim 105 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hsia et al. (US Patent 5498607, Published 03/12/1996) in view of Kagan (US Patent 3389051, Published 06/18/1968) and further in view of Okabe et al. (US Patent 5589192, Published 12/31/1996).

Applicant Claims

Applicant claims a pharmaceutical composition as an ointment, cream, lotion, or emulsion for topical application comprising a compound of formulas II-VIII (as described in the instant claim 82) further comprising a percutaneous enhancer such as polypropylene glycol.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

The teachings of Hsia et al. and Kagan have been disclosed above.

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

The combined teachings of Hsia et al. and Kagan lack a teaching of a composition comprising a compound of a percutaneous absorption enhancer such as polypropylene glycol. This deficiency is cured by the teachings of Okabe et al.

Okabe et al. teaches a topically applicable formulation for local anesthetic. (See abstract). The formulation may further comprise a percutaneous absorption enhancer such as polypropylene glycol. (See column 3, Lines 62-67).

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art at the time of the instant invention to combine the teachings of Hsia et al. and Kagan with Okabe et al. One would be motivated to combine the teachings of Hsia et al. and Kagan with Okabe et al. because Hsia et al. teaches that a percutaneous absorption enhancer can be optionally added to the composition. Therefore, one would have been motivated to add polypropylene glycol as a percutaneous absorption enhancer to the composition of Hsia et al. For the foregoing reasons the instant composition would have been obvious to one of ordinary skill in the art at the time of the instant invention.

Response to Applicants Arguments

Applicant has arguments have been addressed above. For the foregoing reasons the instant rejection of claim 105 under 35 U.S.C. 103(a) **is maintained**.

3. Claim 82, 95, 96, 106, and 107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cohen et al. (US Patent 6020323, Published 02/01/2000, Filed 06/07/1995) in view of Kagan (US Patent 3389051, Published 06/18/1968).

Applicant Claims

Applicant claims a pharmaceutical composition as an ointment, cream, lotion, or emulsion for topical application comprising a compound of formulas II-VIII (as described in the instant claim 82) further comprising a sunscreen.

Determination of the Scope and Content of the Prior Art (MPEP §2141.01)

Cohen et al. teaches a composition that regulates active TNF-α. (See title). A composition comprising low molecular weight heparins is used to inhibit TNF-α and therefore help ameliorate the pathogenic process of atherosclerosis. (See column 15, Lines 43-47 and column 16, Lines 11-14). Such a composition can be formulated to be applied topically and be further supplemented to have protective action of a cosmetic such as sunscreen agents. (See column 24, Lines 26-37 and 42-45).

Ascertainment of the Difference Between Scope the Prior Art and the Claims (MPEP §2141.012)

Cohen et al. lacks a teaching of a composition comprising one of the compounds represented by formulas II-VIII in instant claim 82. This deficiency is cured by the teachings of Kagan.

The teachings of Kagan are disclosed above.

Finding of Prima Facie Obviousness Rational and Motivation (MPEP §2142-2143)

It would have been obvious to one of ordinary skill in the art to combine the teachings of Cohen et al. and Kagan. One would be motivated to combine the teachings because both Cohen et al. and Kagan treat the same condition, atherosclerosis. One would be motivated to combine the compound of Kagan with the composition of Cohen et al. in order to increase cholesterol-lowering activity of the composition of Cohen et al. With regard to the limitation that the compound is intended to reduce skin pigmentation, this limitation is an intended use limitation and is not given patentable weight in a composition claim. For the foregoing reasons the instant composition would have been obvious to one of ordinary skill in the art at the time of the instant invention.

Response to Applicants Arguments

Applicant has arguments have been addressed above. For the foregoing reasons the instant rejection of claims 82, 95, 96, 106, and 107 under 35 U.S.C. 103(a) **is maintained**.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number For the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

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Ali Soroush
Patent Examiner
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